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SUBJECT: NO SMALL PROGRESS: UPDATE ON NANOTECH REGULATION IN THE EU

¶1. (U) SUMMARY: While the European Commission continues to maintain that it's Registration, Evaluation, and Authorization of Chemicals (REACH) regulation provides a sufficient framework for the regulation of nanomaterials in the EU market, a number of directives and legislation single out nanomaterials for specific regulatory oversight. Driven by the views of some Members of the European Parliament (MEPs) that REACH does not adequately address nanotechnology and emerging technologies, the European Parliament has taken the initiative. This cable briefly outlines this legislative action. As the USG sorts out its own views on how to regulate nanotechnology, it should seek to work with European regulators at the earliest opportunity to avoid asynchronous regulation and potential regulatory divergences that may lead to barriers to trade.
END SUMMARY

BACKGROUND

¶2. (U) On April 24, 2009, the European Parliament (EP) adopted a report that urged the European Commission (EC) to "completely overhaul" all regulations related to nanomaterials within two years, treating all nanomaterials as new substances, and to better take into account the risks associated with nanotechnology. The report also called for labeling of nanomaterials in all products, and for better safeguards for workers handling nanomaterials. While the report was non-binding, MEPs sympathetic to the report made it clear they would propose amendments related to nanotechnology as appropriate regulations and directives came to Parliament.

¶3. (U) In response, the Commission, via its second report on the implementation of its 2005-2009 Nanoscience and Nanotechnology Action Plan (http://ec.europa.eu/nanotechnology/policies_ en.html), reiterated its position that existing regulatory frameworks, including REACH, covered nanotechnology "in principle", and suggested consumer and workplace safety would be best enhanced "by improving implementation of current legislation." But the Commission also pledged that it would, by 2011, review and "assess the adequacy of existing legislation", taking into account the "specific points raised by Parliament." The Commission also acknowledged that, "at Parliament's request, specific provisions in relation to nanomaterials have been introduced or are being considered for legislation on cosmetics, novel food and food

additives."

COSMETICS: NANO DEFINED AND TO BE REGISTERED AND LABELED

4.(U) The Regulation on Cosmetic Products (http://ec.europa.eu/enterprise/sectors/cosme tics/documents/directive/), was adopted by the European Parliament March 24, 2009 and will enter into effect in March, 2012. The regulation is a simplification of the existing Directive and its 50 amendments, but in its new iteration it contains significant nano-related content. It defines a nanomaterial as "an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm". The regulation calls for cosmetic products containing nanomaterials to be notified to the Commission six months prior to being placed on the market. It mandates a registry of nanomaterials used in cosmetics. On labeling, the regulation requires all ingredients present in the form of nanomaterials to be clearly indicated in the list of ingredients, with the names of these ingredients followed by the word "nano" in brackets. At this time industry representatives in Brussels tell us they do not have significant concerns with the notification, public registry and labeling requirements. However, industry generally was disappointed the European regulation included a definition and got out in front on the international cooperation on cosmetic regulation process that was working on a more internationally accepted definition for the industry.

NOVEL FOODS: DITTO, BUT FARTHER DOWN THE ROAD

¶5. (U) The revised Novel Foods Regulation

(http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm) is a work in progress, awaiting its second reading before Parliament, expected in February, 2010, although work has been slowed due to a disagreement among commissioners regarding the inclusion of cloned animals in the legislation. Novel foods are defined by the regulation as "those which have not been consumed to any significant degree in the EU before May 1997, when the first legislation on novel foods was established. These can be newly developed products, such as foods produced by new production processes like nanotechnology, but also food that has been consumed traditionally in third countries, outside the EU." The text defines nanomaterials as "intentionally manufactured materials with one or more external dimensions or an internal structure, of order of 100 nm or less." It, too, has a labeling provision for nano consistent with the requirements in the Cosmetics regulation, and also calls for Community-approved specific risk assessment methods prior to the products being placed on the market.

REGULATION ON LABELING: NO NANO DEFINITION, BUT LINKED TO NOVEL FOODS

¶6. (U) In a separate, but related, piece of legislation, the Regulation on the Provision of Food Information to Consumers (http://ec.europa.eu/food/food/labellingnutri tion/foodlabelling/proposed_legislation_en.htm), the Commission seeks to combine Directive 2000/13/EC on the Labeling, Presentation and Advertising of Foodstuffs and Council Directive 90/496/EEC on Nutrition Labeling for Foodstuffs into one instrument which will apply to all foods, whether novel or not. While it does not define nanomaterials, this proposal provides definitions for labeling, packaging, and ingredients, but will be likely be linked to the Novel Foods Regulation through the latter's definition of nano and attendant labeling requirements. The Regulation on Labeling also calls for labeling of nano ingredients for products containing nanomaterials. The European Parliament's Environment Committee is expected to adopt its report at first reading in March at the earliest, followed by the vote in plenary in May or June.

REGULATION ON FOOD ADDITIVES

7.(U) The Regulation on Food Additives (http://ec.europa.eu/food/food/chemicalsafety / additives/prop_leg_en.htm) updates and simplifies current EU legislation regarding food additives and enters into force January, ¶2010. The regulation states that when there is a significant change in the production methods or in the starting materials used for food additives already on the Community list of approved food additives, "or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market." There are no definitions of nanomaterials, nor calls for their labeling, in this regulation.

REACH: THE GREAT UNKNOWN, NANOWISE

¶8. (U) There are no provisions in REACH (http://ec.europa.eu/environment/chemicals/re ach/ reach_intro.htm)referring specifically to nanomaterials. A Commission communication published in June said that since REACH deals with substances, in whatever size, shape or physical state, substances at nanoscale level are therefore covered and its provisions apply. However, Parliament critics of this view point to the minimum tonnage called for under REACH --substances and chemicals manufactured in or imported into the EU in quantities of one metric ton or more per year per company-and claim that nanosubstances in and of themselves would likely not reach the minimum. The Commission is currently drafting updated guidance, expected in early ¶2010. While REACH entered into force in June, 2007, its registration provisions, and thus its ability to capture nanomaterials as substances, do not kick in until December, 2010.

¶9. (U) The Classification, Labeling, and Packaging (CLP) Regulation which complements REACH, updates EU regulations on classification, labeling, and packaging of chemical substances, and entered into effect January, 2009. The regulation provides a general framework for the classification, labeling, and inventorying of "substances with different forms and properties", but does not mention nanomaterials directly.

COMMENT

¶10. (U) The EU is moving forward on defining and regulating nanomaterials in a process largely driven by the Parliament. While there is no unified business community position on the process, industry is closely monitoring the sector specific legislation in the EU and developments in Parliament, Council and Commission. The time is ripe for increased USG engagement, with both the Parliament and the Commission, to shape emerging regulations in a manner that minimizes future transatlantic trade barriers.

KENNARD